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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,782	04/21/2004	S. Michael Owens	D6508	5803

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EXAMINER	
KIM, YUNSOO	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/828,782	OWENS ET AL.	
	Examiner	Art Unit	
	Yunsoo Kim	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *11-13 and 15-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-35 are pending.

2. Applicants' Response to Restriction filed on 11/21/05 is acknowledged.
Applicants' election with traverse of Group I, claims 1-10 and 14 drawn to a chimeric antibody is acknowledged.

Applicants' traversal is based on that the chimeric antibody to PCP is to treat arylcyclohexylamines drug abuse as a sole purpose of the instant invention, thus Groups I and II are not distinct. However, arylcyclohexylamines drug abuse can be treated by materially different product, (i.e. cyano-oxime compound). Thus, the inventions are distinct,

Applicants' traversal is further based on search burden of Groups I and II does not go beyond the search burden of Group I. As referred in the original restriction, these groups are distinct and have acquired a separate status in the art as shown by their different classification. They require non-co-extensive searches. The requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 11-13 and 15-35 are withdrawn from the further consideration by examiner 37 CFR.1.142 (b) as being drawn to a non-elected invention..

Claims 1-10 and 14 drawn to a mouse/human chimeric monoclonal antibody of the SEQ ID NOs: 15-18 are under consideration in the instant application.

3. Applicants' claim for domestic priority under 35. U.S.C. 119(e) is acknowledged.

4. Applicants are invited to submit IDS for consideration.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 8 is indefinite in the recitation of ch- mAb6B5 because its characteristics are not known. The use of ch- mAb6B5 monoclonal antibody as the sole means of identifying the claimed antibody renders the claims indefinite because ch- mAb6B5 is merely a laboratory designation which does not clearly define the claimed product, since different laboratories may use the same laboratory designations to define completely distinct antibodies.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-3 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by the U.S. Pat. No. 6,358,710 B1.

The '710 patent teaches a chimeric antibody derived from monoclonal antibody of human and murine origins (col. 7, lines 4-25).

The '710 patent further teaches the use of human constant regions of IgG2, IgG4 as heavy chain and kappa for light chain, respectively (col. 7, lines 10-15) and administering the antibody with drugs or clearing agent (i.e. pharmaceutically acceptable carrier, col. 8, lines 46-67).

Thus, the prior art teachings anticipate the claimed invention.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-10 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hardin et al. (J. Pharm. Exp. Ther., 285:1113-1122, 21998) as is evidenced by Lim et al. (J. Biol. Chem., 273 (44):28576-28582, 1998) and U.S. Pat. No. 6,358,710 in view of McLean et al. (Mol. Imm., 37:837-845, 2000).

Hardin et al. teach the murine monoclonal antibody mAb6B5 Fab (abstract, p. 1114 under Materials and Methods) binds to phencyclidine.

The complete sequences of mAb6B5 heavy chain and light chain are disclosed in Lim et al. (Fig.1).

It is well known in the antibody therapy art to develop a humanized antibody reduce immunogenicity (the '710 patent, col. 1, lines 35-50).

Hardin et al. do not teach chimeric murine and human antibodies.

However, McLean et al. teach various human expression vectors associated with IgG1, IgG2, IgG3, IgG4, and kappa chain constant regions. The expression vectors constructed to include promotor sequences, leader sequence (2.3-2.5, Fig. 1, 2), drug resistant marker and VDJ cassette. The VDJ cassette can be replaced with any variable region of interest (p. 841, 2.7). The expression vectors are easy to manipulate to replace various variable regions (i.e. Fab of mAb6B5) to produce functional Ig proteins (p. 843, 3.3). The expression vectors used in transfection to generate Ig antibodies (2.5)

As is evidenced in the specification of the instant application, p. 13-14, SEQ ID NO:16 is a chimeric light chain of variable domain of murine antibody and kappa, SEQ ID NO:18 is a chimeric heavy chain of variable domain of murine antibody and IgG2. Human kappa and IgG constant region sequences are well known in the art. Furthermore, the expression vectors taught by McLean et al. includes cDNA encodes constant regions of heavy or light chains, replacing VDJ cassette with known mAb6B5 variable regions results encoding complete SEQ ID NOs: 16 and 18 from SEQ ID NOs: 15 and 17, respectively.

Therefore, one of the ordinary skill in the art would have been motivated to combine the variable region of murine mAb6B5 Fab taught by Hardin et al. and Lim et al. in the expression cassette with built-in human constant heavy and light chain regions taught by McLean et al. to create therapeutically more important chimeric antibody and produce functional Ig.

From the teachings of references, one of the ordinary skill in art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time the invention was made, as evidenced by references, especially in the absence of evidence to the contrary.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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February 3, 2006

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